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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,316	03/29/2007	Alain Aaron	GER0818US	5091

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EXAMINER

FISHER, ELANA BETH

ART UNIT	PAPER NUMBER
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3733

NOTIFICATION DATE	DELIVERY MODE
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01/15/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/583,316	Applicant(s) AARON, ALAIN	
	Examiner ELANA B. FISHER	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-37 is/are pending in the application.
- 4a) Of the above claim(s) 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 22, 2009 has been entered.

Election/Restrictions

2. Newly submitted claim 37 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly submitted claim 37 is directed to a method for producing an intervertebral disc prosthesis. This claim is withdrawn since previously submitted claim 14 had also been drawn to a method for producing an intervertebral disc prosthesis, and was withdrawn by applicant in a prior election/restriction.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 37 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 15 recites the limitation "its central zone" in the seventh and eighth lines of the claim. There is insufficient antecedent basis for this limitation in the claim.

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5. Claim 20 recites the limitation "the space" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.
6. Claim 21 recites the limitation "the space" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.
7. Claim 36 recites the limitation "its central zone" in the seventh and eighth lines of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 15-16, 18-20, 26, 29-30, and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Huang (U.S. Publication 2004/0193273).

Huang discloses an intervertebral disc prosthesis comprising: two plate-shaped or cup-shaped rigid half-shells (1, 2), each of the half shells being configured to be fixed to one of two vertebrae adjacent to an intervertebral disc to be replaced (FIG 1). The two rigid half-shells are disposed on respective sides of a compression pad (3) and secured thereto (FIG 1; Paragraph [0034]). Additionally, a first (2) of said two half shells comprising, in a central zone thereof, a hollow shaft (24) oriented toward a second (1) of said two half shells, the second half-shell comprising, in its central zone, a stud (4)

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oriented toward the first half-shell and penetrating into the hollow shaft (FIG 2) with the compression pad (3) including a portion operatively engaged between the hollow shaft and the stud (FIG 1). The portion of the compression pad comprises a cup-shaped core portion (35) and said compression pad further comprises an outer ring portion (31) disposed outwardly of the core portion (FIG 1) between a free end of the hollow shaft and the second half-shell (FIG 2), such that the core portion (35) fills a space defined between the hollow shaft (24) and the stud (14; FIG 1). The outer ring portion (31) comprises a first surface and a second surface opposed to the first surface, the first and second surfaces of the outer ring portion being respectively secured to inner surfaces of the two half-shells (FIG 1). Additionally, each half-shell (1, 2) comprises, on an outer face, pointed portions (221) intended to promote its primary fixation to a vertebra. Further, each half-shell (1, 2) comprises, on an inner face, lugs (212) for attachment of the compression pad (FIG 1).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (U.S. Publication 2004/0193273).

Claims 22-23:

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Huang discloses a prosthesis according to claim 16 above, however fails to disclose the Shore-A hardness of the outer ring portion (31) and the core portion (35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the Shore-A hardness of the outer ring portion to be between 60 and 100, and additionally the Shore-A hardness of the compressible material inside the shaft to be between 25 and 30, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 25 and 28:

Huang discloses a prosthesis according to claim 16 above, however fails to disclose the material of the core portion (35) and the two-half shells (1, 2). It would have been obvious to one skilled in the art for the core portion to be made of a two-component silicone elastomer crosslinked at ambient temperature, and an encapsulating copolymer whose blowing agent is isobutane and for the two half-shells to be made of a titanium-based alloy, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 32-33:

Huang discloses a prosthesis according to claim 15 above, however fails to disclose that the stud (14) and the shaft (24) have non-circular cross-sections. It would

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have been obvious to one skilled in the art to have the stud and shaft have non-circular cross-sections, such as trapezoidal ones, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a forming edge in the heating portion or clamp. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

12. Claims 17, 21, 24, 27 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (U.S. Publication 2004/0193273) in view of Bainville et al. (U.S. Patent 5,674,294).

Huang discloses an intervertebral disc prosthesis comprising: two plate-shaped or cup-shaped rigid half-shells (1, 2), each of the half shells being configured to be fixed to one of two vertebrae adjacent to an intervertebral disc to be replaced (FIG 1). The two rigid half-shells are disposed on respective sides of a compression pad (3) and secured thereto (FIG 1; Paragraph [0034]). Additionally, a first (2) of said two half shells comprising, in a central zone thereof, a hollow shaft (24) oriented toward a second (1) of said two half shells, the second half-shell comprising, in its central zone, a stud (4) oriented toward the first half-shell and penetrating into the hollow shaft (FIG 2) with the compression pad (3) including a portion operatively engaged between the hollow shaft and the stud (FIG 1). The compression pad includes a core portion (35) operatively engaged between the hollow shaft and the stud (FIG 1) and an outer ring portion (31) disposed operatively of the core portion (FIG 1). The core portion (35) fills a space defined between the hollow shaft (24) and the stud (14; FIG 1). Additionally, the outer ring portion (31) comprises a first surface and a second surface opposed to the first

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surface, the first and second surfaces of the outer ring portion being respectively secured to inner surfaces of the two half-shells (FIG 1).

However, Huang fails to disclose the material of the outer ring portion (31). It would have been obvious to one skilled in the art for the outer ring portion (31) to be made of a polycarbonate urethane type material, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Further, Huang discloses that the core portion (35) comprises a first material and the outer ring portion (31) comprises a second material (FIG 1). However, Huang fails to disclose that the second material is harder than the first material. Bainville et al. disclose a prosthesis comprising first and second rigid half-shells (9, 10) and a compression pad (11). The compression pad comprises a core portion (C2) and an outer ring portion (C3). The core portion (C2) comprises a first material and the outer ring (C3) comprises a second material (FIG 2), such that the second material is harder than the first material (Column 4, lines 16-26). It therefore would have been obvious to one skilled in the art to modify Huang such that the second material is harder than the first material, as is taught by Bainville et al., because it allows the disc prosthesis to have an elasticity that functions like that of the disc that it is replacing (top of Column 4).

13. Claims 31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (U.S. Publication 2004/0193273) as applied to claim 15 above, and further in view of Errico et al. (U.S. Publication 2003/0074067).

Claim 31:

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Huang discloses a prosthesis according to claim 15 above, however fails to disclose that the stud (14) is threadedly engaged in a through-hole in the second half-shell (1). Errico et al. discloses an intervertebral disc prosthesis with a stud (28) that is fixed to a half-shell (10) by being screwed into a through-hole (26). It therefore would have been obvious to one skilled in the art to modify the prosthesis taught by Huang with the fixation means of screwing the stud into the top of the half-shell, as is taught by Errico et al. because screwing the stud into the half-shell is an alternative fixation means which accomplishes the goal of attachment of the stud, while keeping the intervertebral disc prosthesis functionally and mechanically analogous to another fixation means.

Claim 34:

Huang discloses a prosthesis according to claim 15 above, however fails to disclose a coating on the outer surfaces of the half-shells. Errico et al. disclose an intervertebral disc prosthesis that comprises a coating on the outer surfaces of the half-shells (Paragraph [0110]) for ensuring secondary osseous fixation. It therefore would have been obvious to one skilled in the art to modify the intervertebral disc prosthesis taught by Huang with the addition of a coating as is taught by Errico et al. because the coating provides the advantage of further aiding in bone fixation, while keeping the functional and structural features of the prosthesis analogous to that taught by Huang.

Response to Arguments

14. Applicant's arguments filed November 13, 2009 have been fully considered but they are not persuasive.

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Applicant argues that the Huang reference does not teach that the two rigid half-shells are secured to the compression pad. Examiner respectfully disagrees with this argument. According to www.dictionary.com, accepted definitions of "secured" are: to capture and to fasten. In figure 1, Huang shows the compression pad (3) fastened/captured between the two rigid half-shells in figure 1. Accordingly, the rejection over Huang stands.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELANA B. FISHER whose telephone number is (571)270-3643. The examiner can normally be reached on Monday through Friday from 8:30AM to 5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elana B Fisher/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733